International Academy of Compounding Pharmacists

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

Re: FDA Final Rule on New Policies, Requirements and Procedures Pertaining to the Prescription Drug Marketing Act of 1987 and Prescription Drug Amendments of 1992. 64 Fed. Reg. 67720 (December 3, 1999). [Dockets Nos. 92N-0297 and 88N-0258]

Dear Sir/Madam:

Please accept this amendment to the previous comments submitted by the International Academy of Compounding Pharmacists in response to the Food and Drug Administration's ("FDA's") final rule, published December 3, 1999, which implements the Prescription Drug Marketing Act of 1987 (Pub. L. No. 100-293, 102 Stat. 95 (1988)) (the "PDMA"), as modified by the Prescription Drug Amendments of 1992 (the "PDA"). 64 Fed. Reg. 67720 (Dec. 3, 1999) (the "final rule")[1].

This page will replace page 19 previously submitted.

Sincerely,

Shelly Capps

Executive Director

[1] These comments are filed pursuant to a recent Federal Register notice which delayed the effective date of the December 3, 1999 final rule and reopened the administrative record for submission of comments addressing the impact of the final rule on the wholesale distribution system. 65 Fed. Reg. 25639, 25641 (May 3, 2000).

88N-0258

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IACP does not know for certain how many bulk drugs will become unobtainable. IACP estimates that these pedigree requirements could mean the loss of more than 70% of bulk drugs currently used in compounding. Taking into account the numerous areas (e.g. home-health centers, hospitals, veterinary clinics, community pharmacies) in which compounding from bulk drugs occurs, this affects over 10,000 pharmacies and thousands to tens of thousands of patients. The net effect will be that many prescriptions will go unfilled for lack of pedigree information for the bulk drugs necessary for compounding. This impact will be felt both by pharmacists and by patients.

This fear is aptly demonstrated in the SBA's comments which cite to a manufacturer who already had begun to modify its procedures to ensure a timely compliance with FDA's final rule. This manufacturer has notified its customers that "[b]eginning on March 1, 2000, all invoices received without a complete pedigree will not be paid." SBA Comments, p. 4. Under this pattern, smaller distributors and, subsequently, their customers – such as compounding pharmacies – will be unable to obtain the bulk drug substances necessary to compound prescription drugs. It follows that patients would not be able to obtain medicines specifically compounded to meet their individual drug therapies as prescribed by their treating physicians. Thus, as a result of FDA regulating bulk drugs in a fashion never considered by Congress, patients will be deprived of the medication prescribed by their physician. Clearly, this will have a detrimental impact on the public health.

III. FDA'S FINAL RULE DEPARTS FROM 12 YEARS OF AGENCY AND INDUSTRY PRACTICE.